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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,083	04/16/2004	Rashida A. Karmali	134.004	9955

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EXAMINER
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HANDY, DWAYNE K

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/826,083	KARMALI, RASHIDA A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dwayne K. Handy	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/16/04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The information disclosure statement filed September 15, 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it appears to be a duplicate of the IDS submitted on 4/16/2004. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. (5,935,864) in view of Nason (4,978,504) and further in view of Liotta et al. (5,942,407). Schramm teaches a method and kit for collecting samples of liquid specimens for analytical testing. The device is best shown in Figures 2, 4 and 5. The device includes a sample container (5) with an open top (9) and lower capillary end (4), an immunoassay test strip (12) and a vial containing reagents and/or buffers and sealed with a penetrable foil. The lower end of the container has an inwardly extending portion (6) that forms an air-tight seal with the vial. Figures 3-5 show how the device is used. The process is described in column 4, lines 15-42. Capillary volume capacity is given in column 3, lines 29-31. Schramm does not teach a filter in the container, does not cite specific materials of construction, does not teach colorimetric analysis and does not teach a coated capillary.

Nason teaches a specimen test unit the test unit is best shown in Figures 12-15. The device includes top (14) and bottom caps (60) containing a swab sampling element (20) in a housing (30). The housing includes a filter for filtering samples and reagents that flow into the housing and to the collection (bottom) vial. The housing is made of plastic to accommodate deformation (column 5, lines 58-62). Nason discloses colorimetric analysis on reaction products in a vial in column 9, lines 19-25 and column 10, lines 20-25. It would have been obvious to one of ordinary skill in the art to combine the cited features from Nason with the device of Schramm. One would use plastic in order to provide a deformable, yet resilient body structure. One would add the caps to

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seal the body structure. One would add the filters in order to filter mixed components, trap components and/or provide additional reagents as suggested by Nason (column 8, lines 5-15). One would perform colorimetric analysis on the contents of the test device in order to safeguard the operator from contact with samples and reagents (col. 9, lines 24-31). The combined teachings of Schramm and Nason do not teach a coated capillary.

Liotta et al. teaches an immunoassay device for determining analytes in a test sample. In discussing the signal-generating zone of the device, Liotta notes that it would be advantageous if the sample did not have any calcium present so it would be preferable to chelate the calcium with chelating agents. Liotta then goes on to state that the chelating agents could be added during dilution steps, incorporated into a sample collection device or coated onto a capillary pipette (column 12, lines 46-67). It would have been obvious to one of ordinary skill in the art to provide the chelating agent as a coating on the capillary. Schramm and Nason include an immunoassay device. One would add the chelating agents to the input capillary of Schramm and Nason in order to remove materials that would interfere with the immunoassay.

As for the graduated markings on the capillary, it would have been obvious to one of ordinary skill in the art to add markings for volume. Claim 12 recites a plurality of containers having color-coded identifiers. Providing a plurality of containers to perform a number of different tests would be obvious to one of ordinary skill in the art. More containers would allow for more tests.

**Conclusion**


4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Marsden, El Shami et al., Smith and Raybuck et al. show collection devices having a filter. Kelley, Ensing et al., Lewy et al., Kumar et al., Garner and Moyer et al. show device having capillaries coated with reagents.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwayne K. Handy whose telephone number is (571)-272-1259. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DKH  
March 18, 2006

  
Jill Warden  
Supervisory Patent Examiner  
Technology Center 1700